

## DETAILED ACTION

### *Restriction/Election*

1. In response to the communication received on Jan. 19, 2009, from Susan J. Myers Fitch, the election of group I, claims 2, 5, 6, 8, and 9; along with the linking claim, claim 1, is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). This restriction requirement is MADE FINAL.

Claims 1, 2, 4-12, 16-21, 23-38, 40-63, 65-67, and 77-91 are pending. Claims 4, 7, 10-12, 16-21, 23-38, 40-63, 65-67, and 77-91 are withdrawn for being directed to non-elected inventions. Claims 1, 2, 5, 6, 8, and 9 are examined in this Office Action.

The Applicant is reminded that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Drawings***

2. The drawings submitted on June 20, 2005, have been accepted; however, the Applicant has provided replacement drawing for figures 9 and 14 on May 18, 2009. The replacement drawings received on May 18, 2009, have been accepted and replace figures 9 and 14 that were submitted on June 20, 2005

***Specification***

3. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: - - A NUCLEIC ACID WITH ANTISENSE ACTIVITY EFFECTIVE FOR REDUCING EXPRESSION OF RICE PROLAMIN- - .

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1, 2, 5, 6, 8, and 9 are rejected because the claimed invention is directed to non-statutory subject matter.

This claims read on a molecule per se which is found in nature and thus, is unpatentable to Applicants. DNA that occurs in nature in a wild-type rice plant comprises a double stranded nucleic acid molecule wherein one strand encodes a prolamin polypeptide and the other strand is complementary to the coding sequence, therefore the claims, as written, encompass a naturally occurring DNA molecule, and therefore do not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested

that the recitation - - An isolated nucleic acid - - be inserted in place of "A nucleic acid".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. All dependent claims are included in this rejection.

The omitted elements are: the functional elements required for the nucleic acid molecule to have antisense activity; for example, the nucleic acid must be operably linked in antisense orientation to a promoter that functions in rice plants in order for the nucleic acid to have antisense activity; and the nucleic acid will only have antisense activity upon being transferred into a rice plant cell in which an endogenous prolamin protein is expressed.

Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

The term "reduces expression" in claim 1 is a relative term which renders the claim indefinite. The term "reduces expression" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, is the expression reduced relative to other non-transformed rice plants? or is the expression reduced relative to a plant in which a sense construct was introduced rather than an antisense construct? Or is the expression reduced relative to a different tissue in the same plant?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsukawa et al (GenBank Accession AB016505; published on Jan. 9, 1999).

The claims are directed to a nucleic acid molecule having at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide. Because the elements necessary for having antisense activity have not been recited in the claims (see rejection under 35 USC 112, 2<sup>nd</sup> paragraph, above), the Examiner

has not given weight to that particular limitation except to the extent that the potential for having this activity is inherent to any prolamin cDNA.

Mitsukawa et al teach a cDNA encoding a rice prolamin polypeptide (see "Definition" between Locus and Accession on the first page). The cDNA is a double stranded DNA molecule, therefore, it has the complementary strand as well as the coding strand. If the cDNA were linked in antisense orientation to a promoter that functions in rice seeds, then the cDNA would have antisense activity. Therefore, the potential for that activity is inherently part of the cDNA, although the activity is latent until such a time that the nucleic acid is operably linked in antisense orientation and transferred into a rice seed. The cDNA has at least 15 bp, at least 50 bp, and encodes the full-length polypeptide. Although claims 8 and 9 include the limitation that the complementary nucleotides are 50 or less or 30 or less, this limitation does not exclude the full-length cDNA, because the larger nucleic acid molecule (in the parent claim, claim 1) comprises the complementary sequence. Therefore, the use of open language "comprising" renders the claims inclusive of nucleic acids that include a 50-mer or a 30-mer with additional nucleotides, and therefore, the full-length cDNA is not excluded.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirihara et al (US Patent No. 6,326,527; issued on Dec. 4, 2001) in view of Maruta Y. (US Patent No. 5,516,668; issued on May 14, 1996), further in view of Mitsukawa et al (GenBank Accession AB016505; published on Jan. 9, 1999).

The claims are directed to a nucleic acid molecule having at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide. Although claims 8 and 9 include the limitation that the complementary nucleotides are 50 or less or 30 or less, this limitation does not exclude the full-length cDNA or longer nucleic acids, because the larger nucleic acid molecule (in the parent claim, claim 1) comprises the complementary sequence. Therefore, the use of open language "comprising" renders the claims inclusive of nucleic acids that include a 50-mer or a 30-mer with additional nucleotides, and therefore, longer nucleic acids are not excluded.

In the interest of compact prosecution, the Examiner will give weight to having antisense activity, although, the structural components necessary for this activity have not been recited in the claim (see rejection under 35 USC 112, 2<sup>nd</sup> paragraph, above).

Kirihara et al teach transgenic maize plants with inhibition of production of prolamine, a seed storage protein (zein) (see abstract and column 1). They teach antisense sequences (see columns 9 and 10). They teach that a decrease in the expression of seed storage protein in the seed results in an increase in the weight percent of the starch in the seed (see column 28). They teach sequences with more than 15 nucleotides of the prolamine gene (see Figure 2).

Kirihara et al do not teach a prolamin gene from rice.

Maruta Y. teaches a method for decreasing a seed storage protein in seeds (see abstract); and Maruta et al specifically teaches glutelin and prolamin as the major seed storage proteins in rice seeds (see column 1). Maruta claims antisense directed against glutelin (see claims).

Mitsukawa et al teach a cDNA encoding a rice prolamin polypeptide (see "Definition" between Locus and Accession on the first page).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the method taught by Kirihara et al to reduce expression of prolamins in rice. One would have been motivated to do so because Maruta teaches that reducing the protein content in rice grains helps with processing (see column 1, lines 46-49) and that reducing the protein content makes rice grains taste better (see column 1, lines 54-59). Mitsukawa et al teach the actual nucleotide sequence of a rice prolamin cDNA, and one of ordinary skill in the art would have been able to utilize the sequence taught by Mitsukawa et al to



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make antisense constructs effective for inhibition of expression of the endogenous rice prolamin gene. Given the success of Kiriwara et al in inhibiting expression of prolamine in maize and the success of Maruta in inhibiting expression of glutelin in rice, one would have had the expectation of succeeding in the inhibition of expression of prolamin in rice.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638